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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/928,074	09/11/97	FISH	F 07256-024001

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FREDERICK P FISH
SUITE 1400
4225 EXECUTIVE SQUARE
LA JOLLA CA 92037

EXAMINER	
HAYES,R	
ART UNIT	**PAPER NUMBER**
1647	14

DATE MAILED: 07/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applic[illegible]s)
08/928,074	O'Brien
Examiner	**Group Art Unit**
Robert C. Hayes	1647

☒ Responsive to communication(s) filed on *Oct 9, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-31* is/are pending in the application.

Of the above, claim(s) *9-31* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1-8* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims *1-31* are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *5-6*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election of Group I (claims 1-8) in Paper No. 9 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)), and therefore, is made FINAL.

This application contains claims 9-31 are drawn to an invention nonelected with traverse in Paper No. 9. A complete reply to the final rejection must include cancellation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Specification

2. The amendment filed 12/29/97 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Page 11, line 10, contemplated generic sequence, "$LIRX_1NNX_2TX_3X_4X_3X_1X_1$ ", not "$LIX_1NNX_2TX_3X_4X_3X_1X_1$"; thereby, constituting new matter.

Applicant is required to cancel the new matter in the reply to this Office action.

Claim Objections

3. Claims 1 & 4-8 are objected to because reciting sequences by recitation only, versus by the appropriate SEQ ID NO, fails to comply with the Sequence Rules. Appropriate correction is required.

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 & 3-8 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3-5 & 6-9 of U.S. Patent No. 5,696,080. Although the conflicting claims are not identical, they are not patentably distinct from each other because the prosaposin fragment of amino acids 8-29 of SEQ ID NO:3 of '080 is identical to SEQ ID NO:1 of the instant application, and therefore, meets all structural limitations recited in the instant claims.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

No proper antecedent basis nor conception in context with that described within the specification at the time of filing the instant application exists for the new recitation, "$LIX_1NNX_2TX_3X_4X_3X_1X_1$". In contrast, the specification contemplates only generic sequence, "$LIRX_1NNX_2TX_3X_4X_3X_1X_1$ "; thereby, constituting new matter.

6. Claims 1 & 4-8 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In that the specification provides an adequate written description of only two species of a prosaposin receptor agonist (i.e., the peptides of SEQ ID NO: 1 & 2), versus that generically recited as "$LIX_1NNX_2TX_3X_4X_3X_1X_1$", the skilled artisan cannot reasonably visualize what amino

acid sequences constitute a functional generic prosaposin receptor peptide agonist, as claimed. Further, only a "putative prosaposin receptor protein [of]... 54-60 kilodalton (kDa) ... [has been] isolated from whole rat brain, rat cerebellum and mouse neuroblastoma cells..." , and has not been isolated from any other species of animal, or tissue type. Therefore, the specification lacks sufficient written description on what constitutes a generic "prosaposin receptor agonist" sequence; thereby, not meeting the written description requirements under 35 USC 112, first paragraph.

Applicant is directed toward the Revised Interim Utility Guidelines, Federal Register, Vol.64, No.244, pages 71427-71440, Tuesday December 21, 1999.

7. Claims 1-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for peptides consisting of SEQ ID NOs: 1 or 2 as prosaposin receptor agonists, does not reasonably provide enablement for any random peptide with insufficient structural characteristics in which only 5 out of 50 amino acid residues are defined, or any biologically functional equivalents of such putative prosaposin receptor agonist peptides. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification discloses on page 4 that "[o]ne putative prosaposin receptor protein is a 54-60 kilodalton (kDa) protein isolated from whole rat brain, rat cerebellum and mouse neuroblastoma cells using the plasma membrane P-100 fraction." No other tissue sources nor

species that possess the prosaposin receptor are disclosed or known. Except for the disclosure that saposin C or the peptides of SEQ ID NOs: 1-2 bind to these two putative prosaposin receptors (i.e., from rat and mouse), no other "prosaposin receptor agonists" are disclosed. Therefore, the skilled artisan would not known how to assay what constitutes a prosaposin receptor agonist, because even the prosaposin receptor itself that is required to determine such is structurally uncharacterized, and disclosed to exist in only whole rat brain, rat cerebellum and mouse neuroblastoma cells; thereby, requiring undue experimentation to determine how to make and use Applicant's invention.

Further, because a prosaposin receptor "agonist" is merely described as containing the sequence "$LIX_1NNX_2TX_3X_4X_3X_1X_1$ ", the specification fails to define what specific amino acids are critical for defining any prosaposin receptor agonist function that constitutes a sequence of "about 14 to 50 amino acids". In addition, the skilled artisan would reasonably expect that random mutations to any protein/agonist (i.e., as encompassed by the current claim language) would result in inactive prosaposin receptor agonists, which the skilled artisan would therefore not know how to use (i.e., including pharmaceutical compositions thereof; as it relates to claims 4-8), because no activity for such peptides is recited, or specifically disclosed within the specification. For example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence". Rudinger then states on page 6 that "the significance of particular amino acid

sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification as to what minimal structural requirements are necessary for "knowing how to make and use" any prosaposin receptor agonist that merely possesses a consensus sequence defining only 5 amino acid residues does not provide sufficient guidance on what structurally-defined peptides/agonists could be made that retain the desired function of the instant invention, because any such random sequence or mutation within such insufficiently structurally defined peptides/agonists would be predicted by the skilled artisan to adversely affect the three-dimensional conformation of the protein from which it is derived, and therefore, result in inactive receptor agonists, without requiring undue experimentation to determine otherwise.

8. Claims 4-8 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite and incomplete for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unknown what is envisioned as the intended use of these pharmaceutical compositions, since none is specifically recited; especially for determining what an appropriate "unit dosage" entails (e.g., as it relates to claim 8). Therefore, these claims are incomplete.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 1 & 3-8 are rejected under 35 U.S.C. 102(e) as being anticipated by O'Brien et al. (US Patent 5,696,080).

O'Brien et al. teach saposin C-derived fragments of 21-22 amino acid residues (i.e., "having from about 14 to 50 amino acids" which comprise the sequence of SEQ ID NO:25, as well as pharmaceutical compositions of these peptides in "pharmaceutically acceptable carriers (i.e., as it relates to claim 4), in "liposomal form (i.e., as it relates to claim 6), in "lyophilized form (i.e., as it relates to claim 7), in "unit dosage form (i.e., as it relates to claim 8), and using "controlled release materials" (i.e., as it relates to claim 5).

10. Claims 1 & 3-8 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter. These claims were disclosed in U.S. Patent No. 5,696,080 to be invented by both O'Brien and Kishimoto, versus O'Brien alone; thereby, now placing the issue of inventorship in doubt.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

RCH

Robert C. Hayes, Ph.D.
July 13, 2000

Gary L. Kunz

GARY L. KUNZ
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600